Robert A. Mosier CA State Bar No. 164241
Lauren A. Welling CA State Bar No. 291813
Sanders Phillips Grossman, LLC
2860 Michelle Drive, Suite 220
Irvine, CA 92606
Tel: (877) 480-9142
Fax: (949) 861-9352
Email: RMosier@THESANDERSFIRM.COM

Brian J. McCormick, Jr. (to be admitted *pro hac vice*)
Robert Ross (to be admitted *pro hac vice*)
Joel Feller (to be admitted *pro hac vice*)
Matthew A. Casey (to be admitted *pro hac vice*)
Ross Feller Casey, LLP
One Liberty Place
1650 Market Street, Suite 3450
Philadelphia, PA 19103
Tel: (215) 231-3740
Fax: (215) 574-3080
Email: bmccormick@rossfellercasey.com

Attorneys for Plaintiff-Relator Jane Doe

UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES of AMERICA and the STATE OF CALIFORNIA,

Plaintiffs,

ex rel. JANE DOE,

Relator,

v.

AURO PHARMACEUTICALS, INC., CENTRAL DRUGS COMPOUNDING PHARMACY, NAYAN PATEL, YOGESH PATEL, and ASHWIN PATEL,

Defendants.

Civil Action No. SACV16-00800 JFW(PJWx)

FALSE CLAIMS ACT COMPLAINT

FILED UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2)

NOT TO BE POSTED ON PACER

JURY TRIAL DEMANDED

I. NATURE OF THE ACTION

1. Relator Jane Doe ("Relator") brings this action on behalf of the United States of America and the State of California to recover damages and civil penalties for false claims presented, or caused to be presented, by Defendants Central Drugs Compounding Pharmacy, Auro Pharmaceuticals, Inc., Nayan Patel, Yogesh Patel, and Ashwin Patel, to the United States of America ("United States"), and the State of California.

2. This action arises under the provisions of Title 31 U.S.C. § 3729 *et seq.*, known as the False Claims Act ("FCA"), and pursuant to analogous provisions of state and local law, including the California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

3. Under the above-cited statutes, this action seeks to recover treble damages and civil penalties on behalf of the United States and the State of California, for false or fraudulent claims Defendants made for payment, or caused to be made, from government healthcare programs for sterile compounded drugs Defendants knew were produced in facilities not compliant with applicable regulations and/or were medically unnecessary. Relator has documentation and first-hand knowledge thereof.

4. Defendants submitted, or caused to be submitted, claims for reimbursement to federal and state government-funded programs including, without limitation, Medicaid, Medicare, the Federal Employees Health Benefits

Program, TRICARE/CHAMPUS, and the Veterans Administration,[1] and various private health insurance companies in violation of the FCA. The FCA specifically proscribes Defendants' conduct involving falsifying records and manufacturing, selling, and then seeking or conspiring to seek payment from government healthcare programs for sterile compounded drugs Defendants knew were improper and medically unnecessary, and were produced in facility not compliant with applicable regulations.

5. Defendants further knowingly and willfully executed, or attempted to execute, a scheme and artifice to defraud healthcare benefit programs and to obtain, by means of false and fraudulent pretenses, representations, and promises, money owned by, or under the custody or control of, health care benefit programs in connection with the delivery of or payment for health care benefits, items or services, contrary to 18 U.S.C. § 1347 and the FCA.

6. The schemes may also have included improper inducements to healthcare providers and patients for prescriptions.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction to this Court over actions brought pursuant to 31 U.S.C. §§ 3729 and

[1] These government-funded healthcare programs are collectively referred to as "Government Healthcare Programs."

3730. This Court also has subject matter jurisdiction over the counts relating to the California False Claims Act pursuant to 31 U.S.C. § 3732(b), as well as supplemental jurisdiction over the counts relating to the California False Claims Acts pursuant to 28 U.S.C. § 1367.

8. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because acts prohibited by 31 U.S.C. § 3729 occurred in this state and this judicial district. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because at least one act proscribed by 31 U.S.C. § 3729 occurred in this district.

9. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)-(c) because Defendants transact business within this District and because acts proscribed by 31 U.S.C. § 3729 occurred within this District.

III. PRELIMINARY STATEMENT

10. In accordance with 31 U.S.C. § 3730(b)(2), this Complaint is filed under seal and will remain under seal for a period of 60 days or more from its filing date or such other date as the Court so orders, and shall not be served upon Defendants unless the Court so orders.

11. This suit is not based upon prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, lawsuit or investigation, in a Government Accountability Office or Auditor General's report, hearing, audit, or investigation, from the news media, or in any other location as the term

"publicly disclosed" is defined in 31 U.S.C. § 3730 (e)(4)(A), amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1313(j)(2), 124 Stat. 901-902 (2010) ("PPACA"). However, Relator affirmatively disclosed the allegations herein to the United States Department of Justice prior to filing this action.

12. To the extent there has been a public disclosure of the information upon which the allegations of this Complaint are based that is unknown to Relator, Relator is an "original source" of this information as defined in 31 U.S.C. § 3730(e)(4)(B), amended by the PPACA, *supra*, and similar state law provisions.

13. Relator possesses direct and independent knowledge of the information as a result of his role as a consultant with Defendants.

14. Relator voluntarily provided the government with this information prior to filing this action. *See* 31 U.S.C. § 3730(e)(4).

III. THE PARTIES

15. Plaintiff-Relator Jane Doe was hired as a contractor for GXP Consultants, Inc. ("GXP") in October 2015.

16. GXP provides services and support to biotech, pharmaceutical, and medical device manufacturers related to process, design, facility, regulatory and legal compliance, information technology, systems, and clinical trials. Relator's direct supervisor was Ashot Petrossian, Ph.D. ("Petrossian"). Petrossian was the Principal Manager of GXP.

17. Relator was immediately assigned to GXP's project at Defendant Central Drugs Compounding Pharmacy, where he worked until December 2015.

18. Defendant Central Drugs Compounding Pharmacy ("Central Drugs") is a licensed sterile compounding pharmacy with a registered address at 520 W. La Habra Boulevard, La Habra, California. Central Drugs also has a location at 1955 Sunnycrest Drive, Fullerton, California.

19. Defendant Auro Pharmaceuticals, Inc. ("Auro") is an outsourcing facility, manufacturing and distribution company specializing in base compounds, cosmetic products, and medication dispensing systems, and is located at 511 S. Harbor Boulevard, La Habra, California.

20. Upon information and belief, Auro was co-owned by the Patels (defined below) with several unknown outside investors.

21. Defendant Nayan Patel, Pharm. D., is, upon information and belief, a citizen of the State of California. Individual Defendant Nayan Patel serves as the CEO of Central Drugs and the President/CEO of Auro, with business addresses as indicated *supra*.

22. Defendant Yogesh Patel is, upon information and belief, a citizen of the State of California. Individual Defendant Yogesh Patel serves as the CFO of Central Drugs, with a business address as indicated *supra*.

23. Defendant Ashwin Patel, Pharm.D., CCN, is, upon information and belief, a citizen of the State of California. Individual Defendant Ashwin Patel serves as the COO of Central Drugs, with a business address as indicated *supra*.

24. Hereinafter, Individual Defendants Nayan Patel, Ashwin Patel and Yogesh Patel will be collectively referred to as the "Patels."

IV. REGULATORY FRAMEWORK

A. Federal and State Government Health Programs

25. Upon information and belief, federal and state governments, through the Medicaid, Medicare and TRICARE programs, are among the principal purchasers of Defendants' products.

26. Medicare is a federal government health program primarily benefitting the elderly created by Congress in 1965 when it adopted Title XVIII of the Social Security Act. Medicare is administered by the Centers for Medicare and Medicaid Services ("CMS"). Medicare began paying for over-the-counter drugs or for most self-administered prescription drugs after the Medicare Prescription Drug Improvement and Modernization Act of 2003 was fully implemented.

27. TRICARE is the healthcare system of the United States military, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and its dependents. The program operates through various military-operated

hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations and fee-for-service benefits.

28. The Federal Employees Health Benefits Program ("FEHBP") provides health insurance coverage for about 8 million Federal employees, retirees, and its dependents. FEHBP is a collection of individual health care plans, including the Blue Cross and Blue Shield Association, Government Employees Hospital Association, and Rural Carrier Benefit Plan.

29. FEHBP plans are managed by the Office of Personnel Management.

B. The False Claims Act and The Anti-Kickback Statute

30. Originally enacted in 1863, the FCA was substantially amended in 1986 by the False Claims Amendments Act. The 1986 amendments enhanced the Government's ability to recover losses sustained as a result of fraud against the United States. The FCA was again strengthened by additional amendments in 2009 and 2010. The 2009 amendments expanded defendant liability, strengthened retaliation protections, and made it easier for federal, state, and local governments to prosecute FCA actions. The 2010 amendments clarified the definition of who is an "original source" of a FCA disclosure.

31. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim to the Government for payment or

approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1), (2), (7). The FCA empowers private persons who have information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The FCA complaint must be filed under seal without service on any defendant. The complaint remains under seal while the Government conducts an investigation of the allegations in the complaint and determines whether to join the action.

32. Knowingly, manufacturing or selling compounded drugs from a facility not in compliance with the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C.A. § 301, *et seq*., and manufacturing and selling drugs for medically unnecessary uses, by a person who seeks reimbursement from a Federal Government health program for the drug, or who causes another to do so, or billing the Government as if in compliance with these laws, violates the FCA.

33. The FCA also imposes liability upon persons who knowingly make or cause to be made a false record or statement material to a false claim, as well as persons who conspire to "defraud the Government by getting a false or fraudulent claim allowed or paid." 31 U.S.C. §§ 3729(a)(2) and (a)(3).

34. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also covers Medicaid, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of

business reimbursable under a federal health benefits program. The offense is a felony punishable by a fine of up to $25,000 and imprisonment for up to 5 years.

35. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals or business orders, including the prescription of pharmaceuticals, or from receiving remuneration that takes into account the volume or value of any referrals or business generated. 42 C.F.R. § 1001.952(f). Remuneration paid to providers is an illegal kickback when it is paid to induce or reward the drug prescriptions written by physicians. Kickbacks are harmful to public policy because they increase the expenditures paid by government-funded health benefit programs by inducing medically unnecessary use of prescription drugs and excessive reimbursements. Such kickbacks also reduce a patient's healthcare choices as unscrupulous or unknowing physicians steer its patients to various drug products based on the physician's own financial interests rather than the patient's medical needs.

36. Additionally, it is a crime to "defraud any health care benefit program . . . or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services[.]" 18 U.S.C. § 1347.

C. FDA Regulation of Sterile Compounding Pharmacies

37. Traditional drug compounding, or pharmacy compounding, is the practice in which a licensed pharmacist, or a licensed physician, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient based on a prescription for that patient. *See* "Compounding and the FDA: Questions and Answers," http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm (last visited Feb. 2, 2016).

38. This type of compounding is termed "traditional" because it is a long-standing component of pharmacy practice that allows patients to obtain medically viable alternatives when they cannot take a prescription medication in its commercial form. *See Thompson v. Western Sides Med. Ctr.*, 535 U.S. 357, 360-61 (2002).

39. More recently, large-scale compounders, at so-called "outsourcing facilities," have begun producing large quantities of compounded drugs, under the supervision of a licensed pharmacist, without individual patient prescriptions.

40. All outsourcing of the manufacturing/production of compounded medications, whether traditional or outsourced, are regulated by both state and federal authorities.

41. The FDCA provides the FDA with broad authority to regulate the manufacture of new drugs, and prohibits the introduction of unapproved new drugs into interstate commerce.

42. The FDCA defines a "new drug" as a drug "the composition of which is such that such drug is not generally recognized . . . as safe and effective" for the uses prescribed, recommended, or suggested in its labeling. 21 U.S.C.A. § 321.

43. The manufacturer of a new drug must meet the approval and labeling requirements set forth in 21 U.S.C.A. § 355.

44. On November 27, 2013, President Obama signed into law the Drug Quality and Security Act ("DQSA") amending the FDCA specifically to address drug compounding.

45. The DQSA was largely a result of numerous quality issues with medicines related to the growth of these so-called "compounding pharmacies" into national outsourcing suppliers, including a deadly meningitis outbreak tied to a compounding pharmacy in Massachusetts, and was meant to provide the FDA with greater authority over compounding facilities. *See* Adam Rubenfire, "FDA compounding enforcement draws ire from Congress," Modern Healthcare, April 19, 2016, http://www.modernhealthcare.com/article/20160419/NEWS/160419903.

46. Where before there was only the traditional pharmacy as described in Section 503, this pre-existing text now appears as Section 503A (21 U.S.C. §

353a), and a completely new entity is described — the outsourcing facility — in Section 503B. Thus, a Section "503B" entity falls under FDA regulatory authority.

47. A "Compounding Pharmacy" is defined as a state-licensed pharmacy at which drug compounding occurs. *See* 21 U.S.C. § 353a (a)(1).

48. Traditional pharmacy compounding, where a pharmacist receives a prescription for an individual patient and compounds a drug for that patient, is exempted from the FDCA approval and labeling requirements for new drugs. 21 U.S.C.A. § 353a. An "outsourcing facility" is defined under Section 503B as a location or address at which a sterile drug is compounded either by or under the direct supervision of a licensed pharmacist without prescriptions for individual patients, i.e., bulk compounding, and which registers with the FDA under 21 U.S.C. § 353b. 21 U.S.C. § 353b(d)(4)(A).

49. To be exempt from FDA labeling requirements to label products with adequate directions for use, an outsourcing facility must meet the conditions set forth in 21 U.S.C. § 353b.

50. These conditions include compliance with compounding good manufacturing practices ("CGMP") to assure the safety of compounded drugs. *See* 21 C.F.R. § 210.1.

51. The DQSA also places conditions on the materials that an outsourcing facility may compound, including bulk substances, and allows the FDA to inspect outsourcing facilities to ensure compliance. 21 U.S.C. § 353b.

52. Profits for compounded medications have recently skyrocketed, primarily due to the activity of outsourcing facilities. Andrew Pollack, *Pharmacies Turn Drugs into Profits, Pitting Insurers vs. Compounders*, Aug. 14, 2014, The New York Times, http://www.nytimes.com/2014/08/15/business/pharmacies-turn-drugs-into-profits-pitting-insurers-vs-compounders.html.

53. In 2015 alone, TRICARE paid approximately $1.75 billion for compounded drugs. Jonah Bennett, *Tricare Pharmacy Fraud Reaches Epidemic Levels, Prosecutors Open Investigations in Four States*, The Daily Caller, Nov. 9, 2015, http://dailycaller.com/2015/11/09/tricare-pharmacy-fraud-reaches-epidemic-levels-prosecutors-open-investigations-in-four-states/.

54. That payment for compounded drugs was largely responsible for a $2 billion defense health budget deficit in 2015. Tom Philpott, *Compound drugs fleece Tricare, create deep budget hole*, Stars and Stripes, July 30, 2015, http://www.stripes.com /news/us/compound-drugs-fleece-tricare-create-deep-budget-hole-1.360510.

55. Compounded drugs have been at the center of abusive marketing and pricing schemes, as well as kickbacks and fraud. *Id.*

56. It is a violation of the FCA to knowingly administer or bill for, or encourage others to administer or bill for, medically unnecessary compounded medications. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 738 F. Supp. 2d 267, 276 (D. Mass. 2010).

V. DEFENDANTS' MANUFACTURING AND MARKETING SCHEMES PROHIBITED BY THE FCA

57. At the time Relator began working for GXP (October 2015), the company was contracted with, and already working on a project for, Defendants Central Drugs, Auro and the Patels. There were two other consultants working with Petrossian and Relator on the Central Drugs-Auro project.

58. The contract between GXP and the Patels provided for, among other things, GXP to provide consulting services to improve operations at Central Drugs, and to assist with the construction and establishment of a new outsourcing facility located near Central Drugs.

59. The "Partnership Agreement" also called for GXP to be responsible for "operational management" at the new production facility, and "in particular [the] Biopharma Operation."

60. The new facility would become Defendant Auro.

61. Auro describes itself as "a manufacturing and distribution company specializing in base compounds, cosmetic products, and medication dispensing systems." *See* http://www.auropharmainc.com/?page_id=14.

62. On its website, Auro further describes itself as an outsourcing facility. *See id.*

63. Auro claims to serve compounding pharmacies in the U.S. and cosmetic retail companies globally as a wholesale distribution firm. *See id.*

64. Upon information and belief, the original budget for Auro's construction and final organization was $2 million. However, Individual Defendant Nayan Patel expanded the scope of Auro during construction and spent approximately $4.0 million on the compounding pharmacy alone.

65. The focus of GXP's project was to improve the quality systems at Central Drugs and ensure that both Central Drugs and Auro complied with applicable regulations, and in particular that Auro complied with FDCA § 503B as an "outsourcing facility" as defined therein.

66. Project tasks included upgrading process development and equipment with regard to media fills, HVAC validation and environmental monitoring, personnel training, development and enhancement of standard operating procedures, and general facility improvements

67. The GXP-Auro "Partnership Agreement" stated that GXP would provide Auro with the "completed operational capabilities and FDA regulatory licensure" for the following:

- Compounding and Outsourcing Pharmacy;
- Aseptic Filling;
- Sterile Production and Filling; and
- Biopharma Production and Filling.

68. Central Drugs was inspected by FDA during Fall 2015.

69. At the conclusion of the inspection, the FDA investigator issued a Form 483, noting nine (9) observations that the investigator believed could constitute violations of the FDCA and attendant regulations.[2]

70. The observations included various aspects of Central Drugs' operation, including batch manufacturing of sterile drugs and procedures for ensuring sterility.

71. Subsequent to FDA's inspection, GXP worked to review and correct the observations noted in the Form 483 and to prepare a response letter to FDA.

72. At some time during that process, Defendant Nayan Patel told Petrossian that some of the documents the Patels had submitted to FDA had been redacted to hide the productions of a banned substance.

73. Upon information and belief, Auro has not yet been inspected by the FDA. Petrossian's timeline called for Auro to be inspected in late Spring/early Summer 2016, after the facility was completed.

---

[2] An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgement may constitute violations of the FDCA. Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, a Form 483 is presented and discussed with the company's senior management. Companies are encouraged to respond to the Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously. *See* "FDA Form 483 Frequently Asked Questions", FDA.gov, http://www.fda.gov/ICECI/Inspections/ucm256377.htm (last accessed Apr. 21, 2016).

74. However, Individual Defendants Nayan and Yogesh Patel wanted to start production at Auro before an FDA inspection. Upon information and belief, Individual Defendants Nayan and Yogesh Patel did not intend to invite the FDA in for an inspection.

75. This became a contentious issue between Petrossian and the Patels.

76. In December 2015, the Patels terminated GXP's project.

77. Petrossian met with the Patels to determine why the GXP consultants had been dismissed and to discuss the project.

78. The Patels told Petrossian that the GXP consultants had been dismissed because the Patels felt that the consultants' jobs were complete and the consultants had nothing left to do.

79. Petrossian informed the Patels that GXP still had a substantial amount of work to perform to bring Auro into compliance.

80. Individual Defendant Yogesh Patel complained about the cost/expense of work GXP was performing to bring the facility into compliance after the FDA inspection.

81. Individual Defendant Nayan Patel commented that companies that spend too much time on compliance go bankrupt.

82. Upon information and belief, GXP was never brought back by the Patels to resume or complete the project.

83. Petrossian believed and repeatedly told Relator the Patels wanted to begin noncompliant sterile drug manufacturing at Auro before it was properly setup and organized.

84. Petrossian expressed his belief to Relator that Auro was never brought into compliance per GXP's recommendations.

85. In addition, on January 20, 2016, Petrossian informed Relator there was "hanky-panky" occurring at Central Drugs which would "not look good" if "exposed."

86. Petrossian further informed Individual Defendants Nayan Patel, Ashwin Patel and Yogesh Patel, on January 24, 2016, that Auro was still not permitted to produce "non-patient specific compounding" and was not in compliance with FDA regulatory protocols.

87. Upon information and belief, Central Drugs and Auro continue to employ at least 65 staff and ten pharmacists.

88. Upon information and belief, at least 30% of Central Drugs' services are devoted to sterile compounding, and a significantly greater portion of Auro's services are devoted to sterile compounding.

89. Upon information and belief, Central Drugs grosses in excess of $15 million annually, producing 500 to 1,000 vials of compounded drugs daily, and the Auro facility was designed to produce in excess of 5,000 vials of compounded drugs daily.

90. Upon information and belief, Auro and/or Central Drugs have manufactured and sold drugs from noncompliant — and therefore unsafe — facilities that were paid for by any number of healthcare programs, including Government Healthcare Programs.

91. Additionally, upon information and belief, Auro and/or Central Drugs have manufactured and sold drugs that were made using improper production methods and/or for medically unnecessary uses that were paid for by Government Healthcare Programs.

COUNT I
False Claims Act - Presentation of False Claims
31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A), as amended in 2009

92. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

93. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information or with actual knowledge of the falsity of the information, cause and continues to cause, the use of false or fraudulent materials or information to support claims paid by the government for medically unnecessary and/or improperly manufactured compounded drugs manufactured from banned substances in a noncompliant facility.

94. Through the acts described above and otherwise, Defendants and their agents and employees knowingly presented or caused to be presented to the United

States Government false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

95. The United States, unaware of the falsity of the claims and statements made by Defendants, and in reliance on the accuracy of these claims and statements, paid and is continuing to pay or reimburse claims for medically unnecessary and/or improperly manufactured compounded drugs manufactured from banned substances in a noncompliant facility.

96. As a direct result of Defendants' actions as set forth in the Complaint, the United States has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT II
False Claims Act - Making or Using False Records or Statements to Cause Claim to be Paid
31 U.S.C. § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), as amended in 2009

97. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

98. Through the acts described above and otherwise, Defendants and their agents and employees knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2), and, as amended, 31 U.S.C. § 3729(a)(1)(B), in order to get false or fraudulent claims paid and approved by the United States Government.

99. The United States, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and is continuing to pay or reimburse claims for improperly manufactured and/or medically unnecessary compounded drugs manufactured in noncompliant facilities from banned substances, and Defendants falsified records to accomplish the same.

100. As a direct result of Defendants' actions as set forth in the Complaint, the United States has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

COUNT III
False Claims Act – Conspiracy
31 U.S.C. § 3729(a)(3), 31 U.S.C. § 3729(a)(1)(C) as amended in 2009

101. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

102. Through the acts described above and otherwise, Defendants entered into a conspiracy or conspiracies to defraud the United States by getting false and fraudulent claims allowed or paid in violation of 31 U.S.C. § 3729(a)(3), and as amended 31 U.S.C. § 3729(a)(1)(C). Defendants also conspired to omit disclosing or to actively conceal facts, which, if known, would have reduced Government obligations to it or resulted in repayments from it to Government programs.

103. Defendants, their agents, and their employees have taken substantial steps in furtherance of those conspiracies, *inter alia*, by preparing false records, by

submitting claims for reimbursement to the Government for payment or approval, and by directing their agents and personnel not to disclose and/or to conceal its fraudulent practices.

104. The United States, unaware of Defendants' conspiracy or the falsity of the records, statements and claims made by Defendant, its agents and employees, and as a result thereof, has paid and continues to pay millions of dollars that it would not otherwise have paid. Further, because of the false records, statements, claims, and omissions by Defendants and their agents and employees, the United States has not recovered federal funds from Defendants that otherwise would have been recovered.

COUNT IV
False Claims Act - Making or Using False Records or Statements to Conceal, Avoid and Decrease Obligation to Repay Money
31 U.S.C. § 3729(a)(7), 31 U.S.C. § 3729(a)(1)(G) (as amended)

105. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

106. Through the acts described above and otherwise, in violation of 31 U.S.C. § 3729(a)(7), and, as amended, 31 U.S.C. § 3729(a)(1)(G), Defendants and their agents and employees knowingly made, used, or caused to be made or used false records and statements to conceal, avoid, and decrease Defendants' obligation to repay money to the United States Government that Defendants improperly or

fraudulently received. Defendants also failed to disclose material facts that would have resulted in substantial repayments to the United States Government.

107. As a direct result of Defendants' actions as set forth in the Complaint, the United States has been damaged, with the amount to be determined at trial, and is also entitled to statutory penalties.

108. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used, false or fraudulent records or statements, to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States of America in violation of 31 U.S.C. §3729(a)(7).

109. As a direct result of Defendants' actions as set forth in the Complaint, the United States has been, and may continue to be, severely damaged.

COUNT V
California False Claims Act
Cal. Gov't Code § 12651 *et seq.*

110. The allegations of the preceding paragraphs are re-alleged as if fully set forth below.

111. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 *et seq.*

112. By virtue of Defendants' conduct involving manufacturing, selling, falsifying records and then seeking or conspiring to seek payment from government healthcare programs for sterile compounded drugs that Defendants

knew were improper and medically unnecessary, and that were produced in facility not compliant with applicable regulations, described above, Defendants knowingly caused to be presented to the California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims for the improper payment or approval of compounded drugs and used false or fraudulent records to accomplish this purpose.

113. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

114. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants, ordering that:

a. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;

b. Defendants pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendants' actions;

c. Relator be awarded the maximum "relators' share" allowed pursuant to 31 U.S. C. § 3730(d) and similar provisions of the state false claims acts;

d. Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S. C. § 3730(d) and similar provisions of the respective state false claims acts;

e. Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

f. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

g. The United States, the State of California, and Relators recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

4/28/2016

Respectfully submitted,

Robert A. Mosier, CA State Bar No. 164241
Lauren A. Welling, CA State Bar No. 291813
Sanders Phillips Grossman, LLC
2860 Michelle Drive, Suite 220
Irvine, CA 92606
Tel: (877) 480-9142
Fax: (949) 861-9352
Email: RMosier@THESANDERSFIRM.COM

Brian J. McCormick, Jr., Esquire
Robert Ross, Esquire
Joel Feller, Esquire
Matthew A. Casey, Esquire
Ross Feller Casey, LLP
One Liberty Place
1650 Market Street, Suite 3450
Philadelphia, PA 19103
(215) 231-3740
bmccormick@rossfellercasey.com

Attorneys for Relator

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I. (a) PLAINTIFFS (Check box if you are representing yourself ☐)

United States of America and the State of California ex rel. Jane Doe

DEFENDANTS (Check box if you are representing yourself ☐)

Auro Pharmaceuticals, Inc., Central Drugs Compounding Pharmacy, Nayan Patel, Yogesh Patel, and Ashwin Patel

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Orange
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

See attached

Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1. U.S. Government Plaintiff
☒ 3. Federal Question (U.S. Government Not a Party)
☐ 2. U.S. Government Defendant
☐ 4. Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES-For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1. Original Proceeding ☐ 2. Removed from State Court ☐ 3. Remanded from Appellate Court ☐ 4. Reinstated or Reopened ☐ 5. Transferred from Another District (Specify) ☐ 6. Multi-District Litigation

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check "Yes" only if demanded in complaint.)

CLASS ACTION under F.R.Cv.P. 23: ☐ Yes ☒ No ☐ **MONEY DEMANDED IN COMPLAINT:** $

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Violations of the False Claims Act, 31 U.S.C. 3729-3733; Billing Medicare-Medi-Cal for false or fraudulent claims Defendants made or caused to be made for payment

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
- ☒ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/Etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Org.
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Info. Act
- ☐ 896 Arbitration
- ☐ 899 Admin. Procedures Act/Review of Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Vet.)
- ☐ 153 Recovery of Overpayment of Vet. Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment

REAL PROPERTY CONT.
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpratice
- ☐ 365 Personal Injury-Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 American with Disabilities-Employment
- ☐ 446 American with Disabilities-Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus/Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Ret. Inc. Security Act

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405 (g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405 (g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: SACV16-00800

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII. VENUE: Your answers to the questions below will determine the division of the Court to which this case will be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

QUESTION A: Was this case removed from state court? ☐ Yes ☒ No If "no," skip to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question E, below, and continue from there.	STATE CASE WAS PENDING IN THE COUNTY OF:	INITIAL DIVISION IN CACD IS:
	☐ Los Angeles, Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	Southern
	☐ Riverside or San Bernardino	Eastern

QUESTION B: Is the United States, or one of its agencies or employees, a PLAINTIFF in this action? ☒ Yes ☐ No If "no," skip to Question C. If "yes," answer Question B.1, at right.	**B.1.** Do 50% or more of the defendants who reside in the district reside in Orange Co.? *check one of the boxes to the right* →	☒ YES. Your case will initially be assigned to the Southern Division. Enter "Southern" in response to Question E, below, and continue from there. ☐ NO. Continue to Question B.2.
	B.2. Do 50% or more of the defendants who reside in the district reside in Riverside and/or San Bernardino Counties? (Consider the two counties together.) *check one of the boxes to the right* →	☐ YES. Your case will initially be assigned to the Eastern Division. Enter "Eastern" in response to Question E, below, and continue from there. ☒ NO. Your case will initially be assigned to the Western Division. Enter "Western" in response to Question E, below, and continue from there.

QUESTION C: Is the United States, or one of its agencies or employees, a DEFENDANT in this action? ☐ Yes ☒ No If "no," skip to Question D. If "yes," answer Question C.1, at right.	**C.1.** Do 50% or more of the plaintiffs who reside in the district reside in Orange Co.? *check one of the boxes to the right* →	☐ YES. Your case will initially be assigned to the Southern Division. Enter "Southern" in response to Question E, below, and continue from there. ☐ NO. Continue to Question C.2.
	C.2. Do 50% or more of the plaintiffs who reside in the district reside in Riverside and/or San Bernardino Counties? (Consider the two counties together.) *check one of the boxes to the right* →	☐ YES. Your case will initially be assigned to the Eastern Division. Enter "Eastern" in response to Question E, below, and continue from there. ☐ NO. Your case will initially be assigned to the Western Division. Enter "Western" in response to Question E, below, and continue from there.

QUESTION D: Location of plaintiffs and defendants?	**A.** Orange County	**B.** Riverside or San Bernardino County	**C.** Los Angeles, Ventura, Santa Barbara, or San Luis Obispo County
Indicate the location(s) in which 50% or more of *plaintiffs who reside in this district* reside. (Check up to two boxes, or leave blank if none of these choices apply.)	☐	☒	☐
Indicate the location(s) in which 50% or more of *defendants who reside in this district* reside. (Check up to two boxes, or leave blank if none of these choices apply.)	☒	☐	☐

D.1. Is there at least one answer in Column A? ☒ Yes ☐ No	**D.2. Is there at least one answer in Column B?** ☐ Yes ☐ No
If "yes," your case will initially be assigned to the SOUTHERN DIVISION. Enter "Southern" in response to Question E, below, and continue from there. If "no," go to question D2 to the right. →	If "yes," your case will initially be assigned to the EASTERN DIVISION. Enter "Eastern" in response to Question E, below. If "no," your case will be assigned to the WESTERN DIVISION. Enter "Western" in response to Question E, below. ↓

QUESTION E: Initial Division?	INITIAL DIVISION IN CACD
Enter the initial division determined by Question A, B, C, or D above: →	SOUTHERN

QUESTION F: Northern Counties?		
Do 50% or more of plaintiffs or defendants in this district reside in Ventura, Santa Barbara, or San Luis Obispo counties?	☐ Yes	☒ No

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

IX(a). IDENTICAL CASES: Has this action been previously filed **in this court**? ☒ NO ☐ YES

If yes, list case number(s): _____

IX(b). RELATED CASES: Is this case related (as defined below) to any civil or criminal case(s) previously filed **in this court**? ☒ NO ☐ YES

If yes, list case number(s): _____

Civil cases are related when they (check all that apply):

☐ A. Arise from the same or a closely related transaction, happening, or event;

☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or

☐ C. For other reasons would entail substantial duplication of labor if heard by different judges.

Note: That cases may involve the same patent, trademark, or copyright is not, in itself, sufficient to deem cases related.

A civil forfeiture case and a criminal case are related when they (check all that apply):

☐ A. Arise from the same or a closely related transaction, happening, or event;

☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or

☐ C. Involve one or more defendants from the criminal case in common and would entail substantial duplication of labor if heard by different judges.

X. SIGNATURE OF ATTORNEY (OR SELF-REPRESENTED LITIGANT): _____ DATE: 4/28/2016

Notice to Counsel/Parties: The submission of this Civil Cover Sheet is required by Local Rule 3-1. This Form CV-71 and the information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. For more detailed instructions, see separate instruction sheet (CV-071A).

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))

Robert A. Mosier CA State Bar No. 164241
Lauren A. Welling CA State Bar No. 291813
Sanders Phillips Grossman, LLC
2860 Michelle Drive, Suite 220
Irvine, CA 92606
Tel: (877) 480-9142
Fax: (949) 861-9352
Email: RMosier@THESANDERSFIRM.COM

Robert Ross (to be admitted *pro hac vice*)
Joel Feller (to be admitted *pro hac vice*)
Matthew A. Casey (to be admitted *pro hac vice*)
Brian J. McCormick, Jr. (to be admitted *pro hac vice*)
Ross Feller Casey, LLP
One Liberty Place
1650 Market Street, Suite 3450
Philadelphia, PA 19103
Tel: (215) 231-3740
Fax: (215) 574-3080
Email: bmccormick@rossfellercasey.com